

PHARMACY BOARD[657]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 17A.22 and 147.76, the Board of Pharmacy hereby amends Chapter 34, “Rules for Waivers and Variances,” Iowa Administrative Code.

These amendments eliminate duplicative information regarding filing deadlines and contested case procedures that are established in greater detail in 657—Chapter 35, “Contested Cases.” The required contents of the petition for waiver have also been simplified to eliminate information and requirements for information and documentation that have been deemed unnecessary or excessively burdensome, such as a signed release authorizing a person with information regarding a petition to provide the Board with such information.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Notice of Intended Action was published in the June 21, 2017, Iowa Administrative Bulletin as **ARC 3134C**. The Board received no written comments regarding the proposed amendments. The adopted amendments are identical to those published under Notice.

These amendments were approved during the August 30, 2017, meeting of the Board of Pharmacy.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 17A.9A, 17A.22, 22.2, 124.301, 126.17, 147.76, 155A.2, 205.11, 205.13, 272C.3, and 272C.4.

These amendments will become effective on November 1, 2017.

The following amendments are adopted.

ITEM 1. Amend rule 657—34.2(17A,124,126,147,155A,205,272C) as follows:

657—34.2(17A,124,126,147,155A,205,272C) Scope of chapter. This chapter outlines generally applicable standards and a uniform process for the granting of ~~individual~~ waivers from rules adopted by the board in situations when no other more specifically applicable law provides for waivers. To the extent another more specific provision of law governs the issuance of a waiver from a particular rule, the more specific provision shall supersede this chapter with respect to any waiver from that rule.

ITEM 2. Amend rule 657—34.4(17A) as follows:

657—34.4(17A) Criteria for waiver or variance. In response to a petition ~~completed pursuant to rule 34.6(17A) for waiver~~, the board may in its sole discretion issue an order waiving in whole or in part the requirements of a rule if the board finds, based on clear and convincing evidence, all of the following:

1. to 4. No change.

ITEM 3. Amend rule 657—34.5(17A,124,126,147,155A,205,272C) as follows:

657—34.5(17A,124,126,147,155A,205,272C) Filing of petition. A petition for a waiver shall be submitted in writing to the board as follows:

34.5(1) License, registration, or permit application. If the petition relates to a license, registration, or permit application, the petition shall be made in ~~accordance~~ conjunction with the application ~~requirements~~ for the license, registration, or permit in question.

34.5(2) Contested cases. If the petition relates to a procedural rule governing a pending contested case, the petition shall be filed in the contested case proceeding, using the caption of the contested case. A petition cannot be submitted to waive a substantive rule the respondent has been charged with violating in a pending contested case.

34.5(3) Other. If the petition does not relate to a license, registration, or permit application or to a pending contested case, the petition may be submitted to the board’s executive ~~secretary/director~~ director.

ITEM 4. Amend rule 657—34.6(17A) as follows:

657—34.6(17A) Content of petition. A petition for waiver shall include the following information where applicable and known to the petitioner:

1. to 3. No change.

4. The relevant facts that the petitioner believes would justify a waiver under each of the four criteria described in rule 657—34.4(17A). This shall include a signed statement from the petitioner attesting to the accuracy of the facts provided in the petition and a statement of reasons that the petitioner believes will justify a waiver.

~~5. A history of any prior contacts between the board and the petitioner relating to the regulated activity, license, registration, or permit affected by the proposed waiver. This history shall include a description of each affected license, registration, or permit held by the petitioner and any notices of violation, contested case hearings, or investigative reports relating to the regulated activity, license, registration, or permit within the last five years.~~

~~6. 5.~~ Any information known to the petitioner regarding the board's treatment of similar cases.

~~7. 6.~~ The name, address, and telephone number of any public agency or political subdivision which also regulates the activity in question or which might be affected by the granting of the waiver.

~~8. 7.~~ The name, address, and telephone number of any person who would be adversely affected by the granting of a petition for waiver.

~~9. 8.~~ The name, address, and telephone number of any person with knowledge of facts relevant to the proposed waiver.

~~10. Signed releases authorizing persons with knowledge regarding the request to furnish the board with information relevant to the proposed waiver.~~

ITEM 5. Amend rule 657—34.7(17A) as follows:

657—34.7(17A) Additional information and providing notice. Prior to issuing an order granting or denying a waiver, the board may request additional information from the petitioner relative to the petition and surrounding circumstances. ~~If the petition was not filed in a contested case, the board may, on its own motion or at the petitioner's request, schedule a telephonic or in-person meeting between the petitioner and the board's executive secretary/director, a committee of the board, or a quorum of the board. The board may provide notice of a petition for waiver to any person who might be affected by the waiver. The board shall provide public notice of any petitions for waiver by including any petitions for waiver on the agenda of the board meeting during which the petition for waiver will be discussed.~~

ITEM 6. Rescind and reserve rules **657—34.8(17A)** and **657—34.9(17A)**.

ITEM 7. Rescind subrules **34.10(4)**, **34.10(7)**, **34.10(8)** and **34.10(9)**.

ITEM 8. Renumber subrules **34.10(5)** and **34.10(6)** as **34.10(4)** and **34.10(5)**.

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